IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

UNITED STATES OF AMERICA, Plaintiff, v. **JAMES G. COLE,** an individual**, JAMES G. COLE, INC.,** a corporation, and **JULIE D. GRAVES,** an individual, Defendants.	Case No. 3:13-cv-01606-SI **OPINION AND ORDER**

S. Amanda Marshall, United States Attorney, Ronald K. Silver, Assistant United States Attorney, United States Attorney's Office, District of Oregon, 1000 S.W. Third Avenue, Suite 600, Portland, OR 97204; Joyce R. Branda, Acting Assistant Attorney General, Jonathan F. Olin, Deputy Assistant Attorney General, Michael S. Blume, Director, Consumer Protection Branch, Jeffrey I. Steger, Assistant Director, Consumer Protection Branch, and Ann F. Entwistle, Trial Attorney, Consumer Protection Branch, United States Department of Justice, P.O. Box 386, Washington, D.C. 20044. Of Attorneys for Plaintiff.

John J.E. Markham, II, Markham & Read, One Commercial Wharf West, Boston, MA 02110; Krista Shipsey, Law Office of Krista M. Shipsey, 820 S.W. Second Avenue, Suite 275, Portland, OR 97204. Of Attorneys for Defendants.

Michael H. Simon, District Judge.

The Government brings claims against Defendants ("Maxam" or "JGCI")[1] under the Federal Food, Drug, and Cosmetic Act[2] ("FDCA"). The gravamen of the Government's claims is that Defendants distribute in interstate commerce certain articles that are both unapproved new drugs and adulterated dietary supplements. The products are new drugs, the Government argues, because they are distributed with the intent that they be used to treat diseases, including Alzheimer's, HIV, and autism. And they are adulterated dietary supplements, according to the Government, because Maxam lacks the controls over its manufacturing processes mandated by the FDA's Current Good Manufacturing Practice ("cGMP") regulations[3] for dietary supplements. The Government seeks summary judgment and a permanent injunction against Defendants to prevent further violations of the FDCA. For the reasons below, the Government's motion is granted.

STANDARDS

A party is entitled to summary judgment if the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the burden of establishing the absence of a genuine dispute of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant's favor. *Clicks Billiards Inc. v. Sixshooters Inc.*, 251 F.3d 1252, 1257 (9th

[1] Defendant James G. Cole, Inc. ("JGCI") is a privately held Oregon corporation. Defendant James G. Cole is JGCI's president, secretary, and sole board member. Defendant Julie D. Graves was JGCI's general manager and controlled its day-to-day operations—including regulatory compliance protocols—from its inception until November 2013. JGCI does business under several names, including "Advanced Sports Nutrition" and "Maxam Neutraceutics."

[2] Codified at 21 U.S.C. §§ 301-399f.

[3] Promulgated in 21 C.F.R. Part 111.

Cir. 2001). Although "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge," the "mere existence of a scintilla of evidence in support of the [non-movant's] position [is] insufficient" to avoid summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 255 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation and quotation marks omitted).

BACKGROUND

On October 12, 2010, the FDA sent Defendants a letter warning them that their websites were making "disease claims"—claims that their products could be used to diagnose, cure, mitigate, treat, or prevent a disease. By making such claims, the FDA warned, Maxam was selling unapproved new drugs. Some (but not all) of the claims being made were in the form of testimonials from consumers. For example:

- "Try our oral chelation therapy called clathration for autism, Alzheimers, allergies, heavy metal detox and more." Ex. D-3[4] at 1 (non-testimonial).
- "Shown effective against latent residual viruses from old inoculations, measles, mumps, small pox, as well as HPV, EBV, CMV, HIV, etc." Ex. D-3 at 3 (non-testimonial).
- "I am happy to report that after only ten days of being on your product, I am seeing changes in the amount of facial paralysis." Ex. D-3 at 4 (testimonial).

[4] Letter from Charles M. Breen to James G. Cole (Dkt. 26-3).

On November 2, 2010, Defendants responded that they had believed that third-party testimonials were not proscribed disease claims, but that they had now removed all disease claims from their website.

In March 2012, the FDA inspected Maxam's manufacturing facility for compliance with cGMP regulations. The FDA discovered not only several cGMP violations, but also that Defendants continued to make several disease claims on their websites. The twleve cGMP-related findings were provided to Defendants at the end of the inspection in an FDA Inspectional Observations Form 483 ("Form 483"), and the disease claims were pointed out in person during the inspection. On April 19, 2012, Defendants responded to the FDA's findings, assuring the FDA that all disease claims had been removed from their websites and outlining the steps that they would take to come into cGMP compliance.

On September 28, 2012, the FDA sent Defendants another letter warning them that the steps they had proposed were inadequate to bring them into cGMP compliance and that failure to come into compliance could result in an enforcement action. Defendant Cole responded personally on October 19, 2012, asserting with little explanation that Defendants' manufacturing processes had been brought into complete compliance.

From the end of January through early February 2013, the FDA again inspected Defendants' facility. This time, the FDA found sixteen violations of cGMP regulations, as well as, again, several websites making disease claims. Indeed, one such website had been taken offline after the previous inspection and then reinstated with the same disease claims after only a few months. After this inspection, Defendant Cole once again represented that all disease claims would be taken down and that the manufacturing processes would be brought into cGMP compliance.

As of August 19, 2014, however—almost a year after the Government filed this action in September 2013—Maxam's Facebook page still contained the claim that one of Defendants' products was effective to treat "environmentally induced cases of Alzheimer's, Autism, Fibromyalgia, and more." Ex. D-7[5] at 7. Indeed, as late as November 19, 2014, after Defendants filed their brief in opposition to this motion for summary judgment, their website contained claims that their products could "eliminate the toxins produced by unhealthy bacteria" and "counteract even overdose of otherwise lethal drugs." Dkt. 36 Ex. A.[6] And the depositions of Defendants Cole and Graves, taken in early 2014, revealed that Maxam's manufacturing still had not been brought into cGMP compliance.

DISCUSSION

The Government's primary claims are that Maxam has introduced into interstate commerce unapproved new drugs, adulterated dietary supplements, and misbranded drugs. *See* 21 U.S.C. §§ 331(d) & 355(a) (unapproved new drugs); § 331(a) (adulterated dietary supplements and misbranded drugs). Defendants do not contest that they have introduced their products into interstate commerce. The remainder of this Opinion addresses each claim in turn before addressing the Government's request for permanent injunctive relief.

A. Unapproved New Drugs

A product is a "drug" if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). "The vendor's intent is the key element in this statutory definition." *United States v. Storage Spaces Designated Nos. 8 & 49 Located at 277 E. Douglas, Visalia, Cal.*, 777 F.2d 1363, 1366 (9th Cir.

[5] Disease claims found on Defendants' websites during and after the 2013 inspection (Dkt. 26-7).

[6] Disease claims found by Jessica L. Kocian (Dkt. 36-1).

1985). The vendor's intent can be evinced by "labeling claims, advertising matter, or oral or written statements by such persons or their representatives" or other "circumstances surrounding the distribution of the article." 21 C.F.R. § 201.128. In general, express or implied claims that a product can be used to diagnose, cure, mitigate, treat, or prevent a disease are evidence of a vendor's intent that the product be used for such purposes.

A drug is a "new drug" if it "is not generally recognized . . . as safe and effective for use." 21 U.S.C. § 321(p)(1). A new drug may not be introduced into interstate commerce without the approval of the FDA. §§ 331(d), 355(a). Defendants do not argue that their products have been approved by the FDA or are eligible for any exception to FDA approval. *See, e.g.*, § 321(p)(1). Therefore, if Defendants' products are drugs, they are unapproved new drugs.

Consistent with the Government's evidence, Defendants concede that they have in the past made claims that a product can be used to diagnose or treat a disease.[7] Additionally, however, Defendants have marketed their products using "monographs" and "testimonials." "Monographs" list the ingredients purportedly contained in a Maxam product and then republish abstracts of studies claiming that those ingredients might be effective to treat certain conditions. "Testimonials" are allegedly sincere claims from customers that a product successfully treated some condition.[8] Defendants now argue that monographs are permitted under a statutory safe

[7] Defendants' advertising and marketing primarily takes place on the websites from which they sell their products. The Government argues—and Defendants do not dispute—that the intent inquiry encompasses such websites. Defendants have also conveyed disease claims to customers by email and telephone and to doctors in person.

[8] Defendants also appear to refer to their own summaries of such success stories—for example, that a product "has received countless testimonies of recovery for [various diseases]," Ex. C-1 (Dkt. 25-1) at 1 (disease claims discovered by Marion D. dos Santos—as testimonial claims.

harbor, that testimonials are protected speech under the First Amendment, and that they no longer make any other sort of disease claim.

1. Monographs

Defendants argue that their monographs are permitted under 21 U.S.C. § 343(r)(6) as statements that "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, [or] characterize[] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." § 343(r)(6)(A). Such statements, known as "structure–function claims," do not by themselves convert a product into a drug. *See* § 321(g)(1)(D).

Section 343(r)(6), however, establishes three additional requirements that a structure–function claim must meet to qualify for its safe harbor. First, "the manufacturer of the dietary supplement [must have] substantiation that such statement is truthful and not misleading," § 343(r)(6)(B); second, a form disclaimer must be prominently displayed with the statement, § 343(r)(6)(C); and third, the manufacturer must notify the FDA within 30 days of first marketing a supplement with such a statement, § 343(r)(6). Defendants rely on having supplied the required disclaimer. But the Government asserts that the required notification was not made, and Defendants do not dispute this assertion. That fact alone disqualifies Defendants' monographs from the safe harbor of § 343(r)(6).

Moreover, § 343(r)(6) contains its own overriding requirement that "[a] statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." Thus, even a statement that otherwise meets the requirements of § 343(r)(6) is disqualified from the safe harbor if it makes a disease claim. Defendants argue that their monographs "do not make disease claims," but merely "provide identification of studies and resources to further research the ingredients" in their products.

Even if they do not make the claim explicitly, however, Defendants' monographs strongly suggest that the product they describe can treat a disease. *See, e.g.*, Ex. C-4 (listing, *inter alia*, phosphatidylserine as an ingredient of the Maxam product "Neurogen" and republishing claims that phosphatidylserine could treat dementia and Alzheimer's disease). A disease claim made with a wink and a nudge is still a disease claim. To hold otherwise would create an "obviously wide loophole" that would defeat the "high purpose of the Act to protect consumers." *See Kordel v. United States*, 335 U.S. 345, 349 (1948). Accordingly, because Defendants' monographs contain disease claims and because Defendants did not timely supply the required notification to the FDA, Defendants' monographs cannot qualify for the safe harbor of § 343(r)(6).

2. Testimonials

Under the commercial-speech doctrine, speech that proposes a commercial transaction—commercial advertising—receives diminished First Amendment protection. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-68 (1983). False and misleading commercial speech, as well as commercial speech concerning unlawful activities, can be punished or proscribed without violating the First Amendment. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563-64 (1980). Commercial speech that falls outside of these categories is subject to intermediate scrutiny: the restriction must (1) be justified by a substantial government interest; (2) directly advance that interest; and (3) be no more extensive than necessary to serve that interest. *Id.* at 564.

Defendants argue that the testimonials they publish are true and non-misleading and that prohibiting such testimonials is more extensive than necessary to advance any government interest. Defendants' argument fails for two reasons. First, the FDCA does not prohibit disease claims as such; it prohibits the sale of products with a particular intent, and disease claims are

merely probative evidence of that intent. *See* 21 U.S.C. § 321(g)(1)(B); 21 C.F.R. § 201.128. The First Amendment "does not prohibit the evidentiary use of speech . . . to prove motive or intent." *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993). When Defendants incorporate a customer testimonial into advertising material, they endorse and adopt the disease claims made in the testimonial; therefore, the testimonial is evidence of their intent that the product be used to treat disease.

Moreover, commercial speech concerning illegal activity enjoys no First Amendment protection. *See Cent. Hudson*, 447 U.S. at 563-64. Defendants' speech concerns an illegal activity—the introduction into interstate commerce of unapproved new drugs.[9] *See* 21 U.S.C. §§ 331(d), 355(a). Therefore, both because Defendants' speech is being used as evidence of their intent and because it concerns illegal activity, the First Amendment is not violated.

Defendants' past use of disease claims—long after the initial warning letter from the FDA in 2010—and their continued use of testimonials and monographs well into this litigation is ample evidence that Defendants intended that their products be used to diagnose, cure, mitigate, treat, or prevent disease. Defendants' products are therefore drugs, and their introduction into interstate commerce violated the FDCA. *See* 21 U.S.C. §§ 331(d), 355(a).

B. Adulterated Dietary Supplements

The term "dietary supplement" is defined in 21 U.S.C. § 321(ff). For purposes of this action, a dietary supplement is a food that is "intended to supplement the diet" with vitamins, minerals, herbs, amino acids, and so on.[10] § 321(ff). A dietary supplement is deemed to be

[9] Lest this reasoning seem circular, it bears emphasis that Defendants' products are drugs by virtue of Defendants' intent—*not* Defendants' speech. Defendants' speech is evidence of that intent, but the intent is logically prior to the speech.

[10] A product may be sold with the intent both that it supplement the diet *and* that it treat a disease. Accordingly, a product may be both a dietary supplement and a drug. *See United States*

"adulterated" if "it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice [cGMP] regulations." § 342(g)(1). The Government need not show that a supplement deemed adulterated is actually dangerous or contaminated. *See John D. Copanos & Sons, Inc. v. Food & Drug Admin.*, 854 F.2d 510, 514 (D.C. Cir. 1988). An adulterated dietary supplement may not be introduced into interstate commerce. § 331(a).

The FDA's cGMP regulations aim to ensure that a dietary supplement is what it says it is—that it has the identity, purity, strength, and composition it is represented to have. Rather than scrutinize finished products, however, the regulations are directed toward controlling production processes. Of relevance here, manufacturers must: (1) establish precise specifications for the identity, strength, purity, and composition of each component, 21 C.F.R. § 111.70(b); (2) test each incoming shipment of components to ensure it conforms to that specification, 21 C.F.R. § 111.75(a);[11] (3) for each product, detail each step of the manufacturing process *ex ante* in a formal Master Manufacturing Record ("MMR") document, 21 C.F.R. §§ 111.205, 111.210; and (4) each time a batch is produced, document the execution of (and any deviations from) the MMR in a Batch Production Record ("BPR"), 21 C.F.R. §§ 111.255, 111.260.

The Government alleges and has presented evidence that Maxam's manufacturing processes violated each of these requirements. In particular, the Government has shown that

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v. Berst, 2012 WL 4361408, at *4 (D. Or. Aug. 2, 2012) ("When applying the FDCA's definition of drug, courts have found that many products otherwise considered food were drugs based on their advertised use.").

[11] The cGMP regulations differentiate here between "dietary ingredients" and other "components." "Dietary ingredients," as defined in 21 U.S.C. § 321(ff), are vitamins, minerals, herbs, amino acids, and so on. "Components" are all "substance[s] intended for use in the manufacture of a dietary supplement," including dietary ingredients. 21 C.F.R. § 111.3. Manufacturers must test the identity of dietary ingredients themselves, 21 C.F.R. § 111.75(a)(1), but may rely on certificates of analysis from their suppliers for other components if certain conditions are met, 21 C.F.R. § 111.75(a)(2).

Defendants have failed to establish a specification for the identity of each component; failed to verify, using an appropriate and scientifically valid test, the identity of each dietary ingredient; and, depending on the product, either provided incomplete MMRs and BPRs or failed to have MMRs and BPRs entirely.

The outlines of Maxam's manufacturing process are uncontested: (1) Maxam ships raw materials to one Dan West in Rockport, Massachusetts; (2) West combines the ingredients, ferments them, and returns to Maxam a dehydrated powder product; and (3) Maxam then hydrates that powder, packages it, and distributes it in spray bottles.

Defendants claim to "know each ingredient included in the fermentation process for each Maxam product, they keep that information as required in their records and they have provided that information to the FDA." In the next sentence, however, Defendants admit that the "exact measurements" for each ingredient are kept by West and can be obtained from him "if required." This is borne out by evidence submitted by both parties: the MMR for Defendants' "AFX" product, for example, supplies a list of ingredients, but no measurements of any sort. Ex. B-1 (Dkt. 24-1) at 7-8. The ingredient list for Defendants' "PCA" product is similarly deficient. Cole Ex. G (Dkt. 33-7) at 7-8. This alone is a violation of 21 C.F.R. § 111.210(c), which requires that an MMR include an "accurate statement of the weight or measure of each component to be used."

Defendants also advance a conception of their manufacturing process limited to the hydration phase, in which their ingredients are not the materials they send West, but the powders they receive from him. Defendants' MMRs do include measurements for West's powders. But Defendants have neither established the required specifications for those powders nor do they adequately test incoming shipments to ensure they conform to that specification.

Defendants assert that they perform organoleptic testing, microbiological testing, heavy metal testing, and Fourier Transform Infrared Spectrum ("FTIR") testing on the blended powders received from West, but not one of these tests is sufficient to establish the identity—let alone the purity or strength—of the ingredients in blended powders. Heavy metal and microbiological testing test merely for the presence of specific contaminants—e. coli, salmonella, mercury, lead, and arsenic. They do not identify the ingredients contained in a product. Organoleptic testing analyzes a substance using the human senses, observing the color or appearance, texture, flavor, and aroma. The human senses are not sufficient to distinguish between blended powders containing multiple ingredients. For example, two of Defendants' own products, "C-60" and "B-MAX," have identical organoleptic profiles—a fine white powder, strong citrus taste, and no odor—despite having no overlap in ingredients.[12] And FTIR testing produces unique "fingerprints" only for pure compounds, not for blended powders. Thus, as with organoleptic testing, at least two of Defendants' products—"Neurogen" and "AFX"—are indistinguishable using FTIR testing despite having no overlap in ingredients.[13]

In short, Defendants may know what ingredients they send West, but they have no idea what they get back, and therefore no idea what goes into their products.[14] That is a violation of

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[12] Declaration of Cara R. Welch (Dkt. 24) ¶ 20. This fact is uncontested.

[13] *Id.* ¶ 23. Moreover, Defendants merely compare the FTIR fingerprint of a given batch against the FTIR fingerprint of an initial "reference" lot, without having determined the absolute identity of the reference lot by any other means. Therefore, at best, Defendants can determine that a test batch contains the same unknown ingredients as the reference lot. *Id.* ¶ 24. These facts are also uncontested.

[14] Defendant Cole admitted as much during his deposition: He testified that, at least with regard to Maxam's "PCA" product, none of the ingredients sent to West—the ingredients listed on the product label—can be found in the finished product and that the only information Maxam had about the contents of its finished products was based on West's untested assertions. Deposition of James G. Cole (Dkt. 24-2) at 37-39.

cGMP regulations. There is no disputed issue of material fact in that regard: at oral argument, Defendants conceded that their processes did not meet cGMP regulations, and argued only that they could be brought into compliance within 45 days. Defendants' products are therefore per se adulterated. *See* 21 U.S.C. § 342(g)(1).

C. Misbranded Drugs

A drug is misbranded "[u]nless its labeling bears . . . adequate directions for use." 21 U.S.C. § 352(f)(1). Directions are "adequate" if they allow a "layman [to] use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. Such directions, which might include indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures, must be premised on clinical data derived from scientifically controlled investigation—the sort of investigation required for FDA approval. *See United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692, 702 (D. Md. 2001) ("[I]n the absence of investigations or clinical data demonstrating the safety and efficacy of the drugs, there can be no adequate instruction for their *safe* use." (emphasis in original)). Unapproved new drugs, therefore, will frequently also be found to be misbranded drugs. Misbranded drugs may not be introduced into interstate commerce. 21 U.S.C. § 331(a).

Defendants have conducted no controlled studies and collected no clinical data. *See* Deposition of James G. Cole (Dkt. 29-2) at 23:17-25:20, 97:6-8 (containing admissions by Defendant Cole that there are no such studies of Maxam products). Accordingly, Defendants cannot provide adequate directions for a layperson to use their drugs safely. Defendants' drugs are therefore misbranded. *See* 21 U.S.C. § 352(f)(1).

D. Injunctive Relief

The federal district courts are authorized under 21 U.S.C. § 332 to enjoin violations of § 331. Unauthorized new drugs are prohibited under § 331(d) and § 355(a); adulterated dietary

supplements and misbranded drugs are prohibited under § 331(b). The decision to grant a statutory injunction must be "based on appropriate findings supported by the record." *United States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 854 (9th Cir. 1995) (quotation marks omitted).

To obtain a statutory injunction, the Government need only show that "there exists some cognizable danger of recurrent violation."[15] *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *Laerdal Mfg.*, 73 F.3d at 854 (quotation marks omitted). By contrast, if Defendants wish to avoid an injunction, they carry the "heavy" burden of showing that there is "no reasonable expectation that the wrong will be repeated." *W.T. Grant Co.*, 345 U.S. at 633. The following factors are relevant to whether to grant an injunction:

> the degree of scienter involved; the isolated or recurrent nature of the infraction; the defendant's recognition of the wrongful nature of his conduct; the extent to which the defendant's professional and personal characteristics might enable or tempt him to commit future violations; and the sincerity of any assurances against future violations.

Laerdal Mfg., 73 F.3d at 855 (citation omitted). In considering these factors, the Court may infer from a defendant's past violations that "future violations are likely to occur." *See United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 176 (9th Cir. 1987).

1. The *Laerdal Manufacturing* Factors

Here, Defendants have played a cat-and-mouse game with the FDA for more than four years. For example, after the 2010 warning letter, Defendants assured the FDA that they had removed all disease claims, including testimonial claims, from all their websites, including the ASN website, http://ssl.a-s-n.com/. But by the 2012 inspection, disease claims had reappeared on Defendants' websites. At that time, Defendants not only assured the FDA that the claims had

[15] Indeed, the Government need not show that violations of the law are ongoing, or even that they ever began: "the purpose of an injunction is to prevent *future* violations." *W.T. Grant Co.*, 345 U.S. at 633 (emphasis added).

been removed, but that the ASN website had been shut down. In their Opposition, Defendants claim that the ASN website "has never been reactivated" after the March 2012 inspection. In fact, however, that website was reinstated in July 2012 and was once again cited in 2013 for containing disease claims. Defendants yet again assured the FDA that the site would be taken down. It remains active to this day, however, although it currently appears not to have any disease claims.

Defendants' purported attempts to comply with cGMP regulations provides another example of the recurrent nature of Defendants' infractions and Defendants' lack of sincerity. The FDA first inspected Defendants' facility in March 2012. Defendants assert that they have worked diligently since then to come into compliance with cGMP regulations. Almost three years have gone by, however, and despite the FDA twice providing Defendants with detailed, itemized instructions for coming into cGMP compliance,[16] Defendants admit in their Memorandum in Opposition, Dkt. 32 at 12-13, that they still do not know the measurements of the ingredients in their products, in violation of 21 C.F.R. § 111.210(c).

As a final salient example, in December 2014, Defendant Cole posted a message to Maxam's customers on Defendants' website. Dkt. 43. In that message, Defendant Cole wrote that in the event of an injunction, Maxam "plan[ned] on forming a private membership association" to "continue to provide our amazing Maxam technology and products"—in other words, that he intended to flout any injunction. Defendant Cole also stated in his message that "full compliance [with FDA regulations] . . . will be impossible."

Defendants argue that their products are not dangerous and have harmed no one. But that is irrelevant: "The passage of the [FDCA] is . . . an implied finding that violations will harm the

[16] Ex. F-3 (Form 483 provided in 2012); Ex E-2 (Form 483 provided in 2013).

public and ought, if necessary, be restrained." *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 28 (2d Cir. 1972). Moreover, Defendants' argument is further evidence that Defendants do not recognize "the wrongful nature of [their] conduct." *Cf. Laerdal Mfg.*, 73 F.3d at 855. Defendants also claim to have made substantial good-faith efforts toward compliance. Not only is that untrue, it is irrelevant: good faith is not a defense to violations of the FDCA. *Research Labs, Inc.. v. United States*, 167 F.2d 410, 420 (9th Cir. 1948). Based on Defendants' past and ongoing conduct, every single *Laerdal Manufacturing* factor weighs in favor of granting a permanent injunction.

2. The Nature of the Injunction

The Government has provided the Court with a proposed order of permanent injunction based on the FDA's past experience with other defendants who have failed to achieve compliance on their own. Dkt. 23. The Government's proposed order is crafted to guide Defendants into compliance with the FDCA and with cGMP regulations with the assistance of independent experts and review by the FDA. Of note, it provides that Defendants may resume manufacturing and distributing their products after the independent experts and the FDA determine that Defendants have brought their operations into compliance with governing law. Moreover, the Court will retain jurisdiction over this action and under appropriate circumstances Defendants may move the Court to modify the injunction.

Defendants have submitted (and the Court has separately received) a number of letters from Maxam's customers requesting that the Court not grant the Government's requested injunctive relief. *See* Declaration of James G. Cole (Dkt. 41); Dkt. 41-1, 41-2. But whether the general public should have access to unapproved new drugs, misbranded drugs, and dietary supplements that are not manufactured in compliance with cGMP regulations is a policy question

reserved for Congress. The role of the federal courts is merely to apply Congress's answer—the FDCA—to the facts of a particular case.

Defendants ask the Court for 45 days to come into compliance before the permanent injunction takes effect. But Defendants have had four years to come into compliance—and Defendant Cole has admitted that full compliance is "impossible." Dkt. 43 at 1. If Defendants are now sincere about wanting to come into compliance, a 45-day grace period is unnecessary: The Court's separate order provides Defendants with a roadmap lawfully to resume operations without the involvement of this Court.

As Defendants acknowledged at oral argument, there is no genuine dispute that Defendants have violated the FDCA. Moreover, the Government has amply met its burden of showing that there exists a cognizable danger of recurrent violation. Therefore, summary judgment in favor of the Government is appropriate and the Court grants the Government's request for injunctive relief.

CONCLUSION

There is no genuine dispute that Defendants have repeatedly violated the FDCA by introducing into interstate commerce unapproved new drugs, misbranded drugs, and adulterated dietary supplements. Therefore, the Government's motion for summary judgment (Dkt. 22) is GRANTED. A separate order of injunctive relief will follow.

IT IS SO ORDERED.

DATED this 5th day of February, 2015.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge